UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of SCHERING-PLOUGH CORPORATION, a corporation, UPSHER-SMITH LABORATORIES, INC. a corporation, and AMERICAN HOME PRODUCTS CORPORATION, a corporation.	Docket No. 9297

COMPLAINT COUNSEL'S OPPOSITION TO UPSHER-SMITH'S MOTION TO DISMISS THE COMPLAINT

This case is about Schering paying Upsher-Smith and AHP millions of dollars to delay their launch of low-cost generic products that would have saved consumers of K-Dur 20 enormous sums -- but would have drastically reduced Schering's profits. With respect to Upsher-Smith, the complaint charges in part that:

- Schering paid Upsher-Smith $60 million in return for Upsher's agreement to stay off the market until 2001. (Complaint at ¶ 44, 64-65).
- This $60 million payment from Schering induced Upsher-Smith to agree to a later entry date that it would have accepted absent the payment. (¶ 64).
- Upsher-Smith's acceptance of money in exchange for agreement to a later entry date creates a barrier to entry by other generic manufacturers because it serves to delay the triggering of Upsher-Smith's 180-day exclusivity period. (¶ 66).

Upsher-Smith has moved to dismiss the complaint based on its interpretation of a section of a treatise by Professor Hovenkamp. Upsher-Smith appears to concede that the Hovenkamp discussion does not address a case involving a payment not to compete, but simply insists that such a payment "is not relevant under the Hovenkamp standard." (Motion at 7). According to Upsher-Smith, because it was possible that Schering might have won the patent suit, it is lawful for Schering to pay its competitors to stay off the market, as long as the agreement provides for entry at some time prior to the expiration of Schering's patent in 2006.

The sweeping rule that Upsher-Smith proposes is not the law. Nor is it a sound interpretation of Hovenkamp. Patent-holders are entitled to enforce their patents, to refuse to license them to others, and to grant licenses with certain restrictions. But payments not to compete are unlawful – even in the context of claimed patent rights. The complaint here challenges such payments not to compete, whereby Upsher-Smith and ESI agreed to delay entry in return for a share of Schering's monopoly profits. Thus, it is apparent that Upsher's motion to dismiss fails to satisfy the heavy burden to show that complaint counsel "can prove no set of facts in support of his claim which would entitle him to relief." *Conley v Gibson,* 355 U.S. 41, 45-46 (1957).[1]

I. The Complaint's Allegation That Upsher-Smith Agreed to Delay its Entry in Return for a Share of Schering's Monopoly Profits States an Antitrust Cause of Action.

Despite Upsher-Smith's efforts to portray its agreement with Schering as a routine settlement of patent litigation, entitled to the deference ordinarily accorded such agreements, that is not the case. The complaint alleges that a monopolist induced its only potential competitors at

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[1] To prevail, Upsher-Smith must show that the facts alleged by the Commission are insufficient to make out a violation. *TK-7 Corp.*, 1989 FTC LEXIS 32, *3 (1989). The factual allegations of the complaint are presumed to be true and the complaint is to be construed in favor of complaint counsel. *Id. See also* Complaint Counsel's Response to Schering's Motion for Partial Dismissal of the Complaint, at 4-5 (June 25, 2001).

the time (Upsher-Smith and ESI) to delay launching their products by paying a share of its monopoly profits – in Upsher's case $60 million – to secure protection from competition. As the complaint describes, Schering's agreement with Upsher-Smith harmed competition in two ways: first, the payment from Schering bought Upsher's agreement to a later entry date than it otherwise would have accepted (¶ 64); and second, it secured a delay in the triggering of Upsher's 180-day exclusivity period (¶ 66).

Such an agreement is unlawful, even if the monopolist holds a patent that might have been upheld had the parties litigated to a decision in an infringement case. Federal district courts in *In re Cardizem CD Antitrust Litigation*[2] and *In re Terazosin Hydrochloride Antitrust Litigation*[3] ruled that agreements similar to the ones at issue here -- agreements providing for payments from the brand name drug manufacturer to potential generic competitors to stay off the market for a period of time -- were *per se* antitrust violations.

Notwithstanding these cases, however, Upsher-Smith contends that the complaint in this case is defective because it does not plead that the agreement between Upsher-Smith and Schering is a more anticompetitive outcome than a Schering victory in the patent case. The complaint, of course, specifically alleges that the Schering/Upsher-Smith settlement creates a barrier to entry by other generics. Schering itself observed at the last pre-trial hearing that this would not have occurred if Schering won the patent case, stating that "I think it's also common ground, Your Honor, that if the first filer is sued and loses the patent case, that the first filer gets

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[2] 105 F. Supp. 2d 682 (E.D. Mich. 2000), *appeal docketed*, No. 00-2483 (6th Cir. Dec. 19, 2000).

[3] 2000 U.S. Dist. LEXIS 20477 (S.D. Fla. 2000), *appeal pending.*

no exclusivity."[4] Upsher-Smith's argument has a more fundamental problem, however, for Supreme Court cases such as *United States v. Masonite*, 316 U.S. 265 (1942), make it clear that the broad rule that Upsher-Smith proposes is not the law.

In *Masonite*, competing manufacturers of wallboard entered into agreements with Masonite settling its claims that their products infringed its patents. Under the terms of the agreements, the manufacturers withdrew their products from the market and instead distributed Masonite's product, at prices set by Masonite. Although the Court assumed that Masonite's patents were valid and that the competing manufacturers had not succeeded in developing non-infringing products (*id.* at 276, 281-82)[5] – thus suggesting that Masonite would have won infringement suits had it pursued them – the Court condemned the agreements. The Court found that the price fixing agreements with Masonite, which assured all sellers would receive the monopoly price, was "a powerful inducement to abandon competition" (*id.* at 281), and unlawful notwithstanding Masonite's patents. The Court also condemned anticompetitive agreements between parties with an unresolved patent dispute in *United States v. New Wrinkle, Co.*, 342 U.S. 371 (1952) and *United States v. Line Material*, 333 U.S. 287 (1948), notwithstanding the possibility that the patent holder might have been able to secure a court judgment that would

[4] Pretrial Hearing Transcript at Page 12, lines 16-19 (July 25, 2001).

[5] Masonite settled with Celotex after the Masonite patents were held valid and infringed in the court of appeals. 316 U.S at 268. All the wallboard companies entered into agreements with Masonite that acknowledged the validity of Masonite's patents. *Id.* at 271, 280. The Supreme Court accepted factual findings of the district court that: the companies had tried and failed to develop a product that did not infringe Masonite's patents; that the agreements had not deterred them from efforts to design around Masonite's patents, and that they would terminate their agreements with Masonite if they succeeded in developing a non-infringing product. *Id.* at 280-281.

have excluded all competition from the alleged infringer for the life of the patent.

Upsher-Smith endeavors to escape the Supreme Court's decisions in *Masonite, New Wrinkle*, and *Line Material* by insisting that these cases are fundamentally different because they involve price fixing. But as we noted in response to Schering's motion to dismiss (at pp. 10-12), these cases reflect the principle that patent-holders may not induce competitors to abandon competition with their own products through an arrangement to share monopoly profits. In these Supreme Court cases, the sharing of monopoly rents was achieved through price fixing. In the case of Schering's agreements with Upsher-Smith and ESI, it was achieved through a market allocation agreement secured by payments from the patent-holder to the alleged infringers. Both amount to paying competitors to abandon their competition.

If Upsher-Smith's rule were correct – that to be unlawful a patent settlement must be a more anticompetitive outcome than the patent-holder winning the lawsuit -- then *Masonite, New Wrinkle*, and *Line Material* would have been decided differently. A group of competitors selling a product at a fixed price is no worse than these sellers being excluded from the market entirely, because in the first instance the sellers can still compete on non-price terms. Indeed, as Judge Posner has observed:

> It would be a strange interpretation of antitrust law that forbade competitors to agree on what price to charge, thus eliminating price competition among them, but allowed them to divide markets, thus eliminating all competition among them.[6]

The agreement here effectively eliminates all competition, including price competition, for K-Dur 20 until September 2001.

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[6] *Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995).

Finally, as we noted at the outset, Upsher's motion to dismiss is based not on a rule articulated in any case, but instead on its interpretation of a section in Professor Hovenkamp's treatise. Upsher-Smith suggests that a discussion in a footnote on page 13 of our response to Schering's motion to dismiss implies that we accept Upsher-Smith's interpretation of Hovenkamp. We do not. Upsher-Smith's interpretation applies the Hovenkamp analysis in a context never discussed by Hovenkamp and contradicts existing case law.

The import of the Hovenkamp section upon which Upsher-Smith relies is not clear. The discussion appears to focus on cases involving potentially conflicting or "blocking" patents.[7] Such cases present unique considerations because of the possibility that each party's patent rights could block the other from the market, with the result that no one can enter. Furthermore, as we noted when Schering invoked Hovenkamp, one aspect of the standard he articulates requires that a settlement be a "reasonable accommodation," but he does not explain that criterion. Upsher-Smith suggests that "it appears" that this requirement merely means that the agreement must relate to the patent issues involved in the litigation. As we noted in our response to Schering's motion to dismiss, however, we believe that an agreement to share monopoly profits in exchange for delaying competitive entry cannot be a reasonable accommodation, given the existing case law.

In any event, what is clear is that nowhere in the section does Hovenkamp address the

[7] While the section contains a discussion of the *Clorox* case, which involved an assertion of trademark infringement, the section is replete with references to cases "conflicting intellectual property rights" and settlements involving cross-licensing or pooling of patents. *See, e.g.*, Section 2046 at p. 262 (referring to cases of "conflicting intellectual property rights" and settlements involving cross-licensing or patent pooling); at p. 263 (posing hypothetical where "A and B have developed potentially conflicting patents"); at 266 & n. 15, 16, 17, 19 (discussing cases involving potentially conflicting patents).

situation presented here – where a patent holder has paid the alleged infringer to stay off the market. Many have noted that such "reverse payments" are highly unusual in patent settlements.[8] Thus, it is perhaps not surprising that the Hovenkamp discussion does not address them, particularly since the section pre-dates the federal court decisions condemning the agreements involving *Abbott/Geneva* (Terazosin) and *Hoechst/Andrx* (Cardizem CD), as well as the Commission's enforcement actions in those matters. There is no reason to think that Professor Hovenkamp intended to apply the analysis in that section to the kind of agreement present here.

Upsher-Smith's attempt to dismiss the significance of the payment for delay by referring to *Carpet Seaming Tape Licensing v. Best Seam, Inc.*, 694 F.2d 570 (9th Cir. 1982), does not further its argument. That case merely reflects the straightforward proposition that a procompetitive agreement is not rendered unlawful simply because there are other possible arrangements that could further enhance competition.[9] The fundamental difference here is that

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[8] *See, e.g.*, Robert J. Hoerner, *Antitrust Pitfalls in Patent Litigation Settlement Agreements*, 8 Fed. Circuit B.J. 113, 122, 123 (Summer 1998) (emphasis supplied):

> Were one competitor to agree to pay, and to pay, another to leave a business in order to eliminate its competition, all would accept that ordinarily there had been a per se antitrust violation. A similar anticompetitive result can be achieved, in a more innocent-appearing manner, if the patent owner pays money, or gives an infringer something of value, to be subject to a patent injunction, especially if the injunction is broader than the claims. *Ordinarily, consideration flows the other way; the infringer pays some amount to the patent owner* for past infringement and then agrees to an injunction for the remaining life of the patent or is granted a license. . . . . If the patent owner pays the infringer, and if the infringer settles by accepting an injunction, or agrees to abandon the field, scrutiny is warranted.

[9] The agreement at issue in that case was a patent pooling agreement involving patents that the trial court had found to be blocking. The appellate court held that an agreement to pool patents and exploit them through a uniform royalty rate, as the parties had done, was lawful. 694 F.2d at 579-580.

Upsher's agreement to delay entry in exchange for payments from Schering is anticompetitive, not merely "less procompetitive" than some alternative arrangement. The point is not that Upsher-Smith and Schering "could" have negotiated an earlier entry date, as Upsher-Smith suggests. (Motion at 5). Rather, as the complaint (¶ 64) alleges and is assumed for this motion, the parties *would have agreed to earlier entry absent the payment.* Moreover, the actual settlement has a later entry date than would have been expected had the parties pursued the litigation. In other words, the parties, by entering into the settlement harmed consumers, making them worse off than if the settlement had not occurred.

In sum, Upsher-Smith's reliance on Hovenkamp is misplaced, as the discussion plainly doesn't address cases involving payments not to compete. And even if it were to apply, such arrangements would not satisfy the Hovenkamp requirement the settlement be a reasonable accommodation of the litigants' dispute, particularly in light of the contrary case law. Furthermore, the Schering/Upsher-Smith settlement is more anticompetitive than a Schering victory because it preserves a barrier to competition by other generic firms.

II. Upsher's Other Challenges to the Complaint Should Be Rejected.

Upsher devotes approximately one page at the end of its argument to urge dismissal of the complaint allegations concerning (a) the exclusion of other generic entrants and (b) the unlawful collateral restraint on entry with a non-infringing product. These arguments are plainly wrong.

First, Upsher-Smith asserts (as did Schering in its motion to dismiss) that the challenged agreement has no exclusionary effect on third parties. Then, (like Schering) Upsher-Smith tries to shoehorn this incorrect argument into a claim of *Noerr* immunity. Upsher-Smith also throws in for good measure a reference to "principles of causation and antitrust injury" (Motion at 8), though it does not explain why those principles, which are ordinarily applied in analyzing damage actions, are relevant here in this action for injunctive relief.

We can dispose of Upsher-Smith's brief *Noerr* argument with equal dispatch. The *Noerr* doctrine protects petitioning for governmental action.[10] As the Court of Appeals for the D.C. Circuit recently observed in *Andrx Pharmaceuticals v. Biovail Corp. International*, 2001 U.S. App. LEXIS 17072, *53-56 (July 31, 2001), private settlement agreements do not constitute petitioning or conduct "incidental" thereto, and are not *Noerr* protected.[11] And whatever lobbying Upsher-Smith might do in the future will not retrospectively confer *Noerr* immunity on its agreement with Schering.[12]

As to the causation argument itself, as we explained in our response to Schering's motion to dismiss (at pp. 18-19), payment to secure an agreement to delay the triggering of the 180-day exclusivity period that the Hatch-Waxman confers on first generic applicants directly harms

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[10] *See, e.g., Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 56 (1993) (*Noerr* immunity applies to those who petition the government); *MCI Communications Corp. v. AT & T,*708 F.2d 1081, 1159 (7th Cir. 1983) ("The Noerr-Pennington doctrine is concerned solely with the right to attempt to influence government action.").

[11] The D.C. Circuit, considering the Hoechst/Andrx agreement, rejected the argument that a private settlement was incidental to litigation, and stated:

> The Agreement is not unlike a final, private settlement agreement resolving the patent infringement litigation by substituting a market allocation agreement. Such a settlement would not enjoy Noerr-Pennington immunity and neither does the Agreement here.

2001 U.S. App. LEXIS 17072 at *56.

[12] As Judge Posner noted in *In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 789 (7th Cir. 1999), "the doctrine does not authorize anticompetitive action in advance of government's adopting the industry's anticompetitive proposal."

competition and consumers -- in a way that the statutory scheme does not. Various cases[13] (and the FDA[14]) have held as much, recognizing that such settlement agreements amount to a manipulation of the statutory scheme. Most recently, the D.C. Circuit in *Andrx v. Biovail* reversed a district court decision that any injury to Biovail (the second generic filer) could not be attributed to the agreement between first filer Andrx and Hoechst, given the delay period prescribed by Hatch-Waxman. 2001 U.S. App. LEXIS 17072 at *25. "[W]e disagree," the court stated, "with its conclusion that any injury Biovail might plead would be caused by 'the existence of a troublesome statutory scheme.'" The Court of Appeals went on to state that "the statutory scheme does not envision the first applicant's agreeing with the patent holder to delay the start of the 180-day exclusivity period." *Id.* at *27-28. Noting that payments from Hoechst allowed Andrx to "receive[] the benefit of the 180-day exclusivity period without starting the clock," (*id.* at *28), the court concluded:

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[13] *See, e.g.*, *Biovail Corp. International v. Hoechstaktiengesellschaft*, 49 F.Supp.2d 750, 768 (D. N.J. 1999) (rejecting defendants' argument that antitrust claim against the Hoechst/Andrx agreement was merely "frustration with the statutory exclusivity period" and finding that the complaint challenged an alleged "abuse of the statute."); *In re Cardizem CD Antitrust Litigation*, 105 F. Supp.2d 618, 658 (E.D. Mich. 2000) (Hatch-Waxman Amendments permit certain unilateral action but do not authorize agreements to restrain trade); 663 (same).

[14] The FDA has stated:

> [A] successful strategy to extend market exclusivity can mean tens of millions of dollars in increased revenue for an innovator firm. Under such circumstances, it can be mutually beneficial for the innovator and the generic company that is awarded 180 days of generic exclusivity to enter into agreements that block generic competition for extended periods. This delayed competition harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments.

Proposed Rule on 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42882-83 (August 6, 1999).

> Although the 180-day provision of the Hatch-Waxman Amendments legally barred [Biovail] from selling its product, Andrx's manipulation of the exclusivity period trigger date extended the legal bar. *Id.* at *29.

Upsher also suggests that the complaint allegations regarding the exclusionary effect of its agreement with Schering are "wrong as matter of law" because the Commission did not explain in the complaint the details of the so-called "court decision trigger" under Hatch-Waxman. Upsher-Smith is correct that a court ruling in any case that Schering's '743 patent is invalid or not infringed would trigger the start of Upsher-Smith's exclusivity period. That fact, however, in no way undermines the charge that Upsher-Smith's agreement to delay its triggering of the exclusivity period (which it could otherwise do by commencing commercial marketing of K-Dur 20), erected a barrier to generic competition. The court decision trigger simply means that the barrier to entry by later filers is not airtight or ironclad. Indeed, the possibility of a court decision trigger makes Schering's agreement with ESI important, because by paying ESI to settle Schering avoided the possibility that ESI might obtain a decision that would trigger Upsher-Smith's 180-day exclusivity period.

A barrier to entry harms competition even if is not complete. And the D.C. Circuit in *Andrx v. Biovail* rejected the argument that the exclusionary effects of an agreement by a first generic filer to delay the triggering of its exclusivity period could be easily overcome by virtue of the alternative court decision trigger. As the court noted, the time required to bring and obtain a decision in a declaratory judgment action seeking an adjudication of the brand drug company's patent claims makes this option "less than 'fully available.'" 2001 U.S. App. LEXIS 17072 at *35.

Finally, Upsher-Smith offers a brief objection to the complaint allegations that it agreed not to market even a clearly non-infringing generic version of K-Dur 20. Unlike its main argument, here Upsher-Smith does not argue that a bona fide patent dispute legitimizes this type of agreement. Instead, Upsher protests that the complaint does not allege that this agreement had "any practical effect" because it does not allege that Upsher-Smith was likely to have undertaken to market such a product prior to September 2001. No such allegations are needed to state a claim. Even if we were to accept for the sake of argument Upsher-Smith's effort to assert facts outside the complaint relating to its intent and ability to develop an alternative non-infringing product (improper in the context of a motion to dismiss),[15] the complaint still pleads a cause of action. An agreement not to compete with a non-infringing product – in exchange for a share of Schering's monopoly profits – is so plainly anticompetitive and so obviously lacking in any plausible justification that no more is needed. This is a naked market allocation agreement, unlawful on its face even assuming Upsher-Smith's facts to be true, and is suitable for summary condemnation. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990).

CONCLUSION

Upsher-Smith's assertion that its $60 million dollar agreement to delay offering consumers a lower-cost generic alternative to K-Dur 20 was "a far less anticompetitive outcome than a Schering win would have been" is incorrect and based on a flawed legal argument. Likewise, its claim that this agreement "does not place any restraint upon any other generic

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[15] If Upsher-Smith wishes to make factual assertions beyond the complaint, it should file a summary judgment motion with evidence demonstrating a lack of any material fact in dispute. *See* Wright and Miller, 5A *Federal Practice and Procedure* § 1366.

manufacturer" is wrong and directly contradicts Paragraph 47 of the Complaint. Upsher-Smith has failed to meet its burden to demonstrate that the Commission's complaint fails to state a cause of action. The Motion to Dismiss the Complaint should be denied.

Respectfully Submitted,

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Dated: August 8, 2001

CERTIFICATE OF SERVICE

I, Robin Moore, hereby certify that on August 8, 2001, I caused an original, one paper copy and an electronic copy of *Complaint Counsel's Opposition to Upsher-Smith's Motion to Dismiss* to be filed with the Secretary of the Commission, that two paper copies were served by hand upon The Honorable D. Michael Chappell, Administrative Law Judge, and that one paper copy was served upon the following persons by overnight delivery and facsimile:

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